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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,786	11/08/2001	Simon Robitaille	3648.028	2013

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EXAMINER	
CHORBAJI, MONZER R	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,786	ROBITAILLE ET AL.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☒ Claim(s) *24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This non-final action is in response to the amendment received on 05/20/2005

Claim Objections

1. Claims 5-6 are objected to because of the following informalities:

In claim 5, line 2, please replace "," with ".", for example, replace "0,1" with "0.1". The same applies to claim 6.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-8, 11-13 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carman et al (U.S.P.N. 6,284,193) in view of Jacobs et al (U.S.P.N. 6,325,972).

With respect to claims 1 and 12, the Carman reference teaches a method and an apparatus (col.1, lines 9-12) using ozone-containing gas (col.2, lines 25-30) to sterilize medical articles including the following: providing a sterilization chamber (1), placing articles in the chamber (col.7, lines 29-30), sealing the chamber (col.7, lines 30-31), applying vacuum to the chamber (col.7, lines 53-56 and line 5) such that the range of the Carman vacuum (upon conversion from pounds per inch square to millbar) as disclosed by the specification (paragraphs 00018 and 00019 and paragraph 00030) intrinsically results in lowering the boiling point of water in the sterilization chamber to a temperature below the temperature in the chamber, supplying water to humidify the atmosphere close to saturation point within the chamber (col.7, lines 56-58 and line 12), supplying ozone-containing gas to the chamber (col.7, lines 59-64 and line 6), maintaining the vacuum in the chamber over the treatment time interval (col.7, lines 64-67 and col.8, line 1) and releasing the vacuum in the chamber (col.8, lines 2-3). The Carman reference does not teach 100% relative humidity (saturation point), however, the Carman reference teaches a relative humidity of 98%, which is equivalent to approaching saturation point. However, with respect to claims 1 and 12, the Carman

reference fails to disclose equalizing the temperature of the articles and the chamber atmosphere prior to applying vacuum application step in order to prevent condensation of water on the articles. The Jacobs reference, which is in the art of sterilizing medical articles by vaporizing sterilants, teaches drawing a vacuum then introducing fresh air (col.9, lines 61-67 and col.10, lines 1-2) into the chamber prior to adjusting the pressure in the sterilization chamber (col.10, lines 4-6 and line 11-13) to the sterilization pressure such that intrinsically preventing condensation. The specification on page 7 teaches that equalization is applying vacuum then injecting air just as shown in the Jacobs reference. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus of the Carman reference by adding an equalization step as taught by the Jacobs reference in order to raise the pressure within the chamber back to atmosphere (col.9, line 67 and col.10, lines 1-2).

With respect to claim 2, the Carman reference fails to disclose equalizing the temperature of the articles and the chamber atmosphere and any components and materials in contact with the atmosphere; however, the Jacobs reference, which is in the art of sterilizing medical articles by vaporizing sterilants, teaches drawing a vacuum then introducing fresh air (col.9, lines 61-67 and col.10, lines 1-2) into the chamber. The specification on page 7 defines equalization as applying vacuum then injecting air resulting in the chamber, the articles and the atmosphere in the chamber all being at the same temperature. The vacuuming and the admission of air in the Jacobs reference is intrinsically capable of the chamber, the articles and the atmosphere in the chamber all being in the same temperature. As a result, it would have been obvious to one having

ordinary skill in the art at the time the invention was made to modify the method and apparatus of the Carman reference by adding an equalization step as taught by the Jacobs reference in order to raise the pressure within the chamber back to atmosphere (col.10, lines col.9, line 67 and col.10, lines 1-2).

With respect to claims 3-8, 11, 13 and 15-22 the Carman reference teaches the following: chamber temperature of 25 degree Celsius (col.7, lines 24-25 such that 80 degrees Fahrenheit is equal to 27 degree Celsius), vacuum pressure of 0.69 millbar (0.01 lb/in^2 is equal to 0.69 mbar and col.7, lines 52-56), humidity level of 98 % (col.4, lines 16-19), means for destroying ozone (9), vacuum within the chamber is maintained for a preselected time interval (col.7, lines 64-67 and col.8, line 1) such that the vacuum (col.7, lines 54-55) is adjusted to any desired value within the disclosed range (col.7, lines 54-56), an ozone generator (6), a pump (5) that generates vacuum range that includes 55.3 mbar and higher (col.7, line 55), an intrinsic means for controlling the concentration of ozone in order to maintain such a concentration (col.4, lines 36-41) and adjusting the vacuum pressure (col.7, lines 42-44 including a value for maintaining vacuum).

With respect to claim 23, the Carman reference teaches that all parameters of the sterilization process are controlled by a programmable industrial process controller (8). This teaching intrinsically includes feedback mechanisms, for example, based on readings from ozone level and vacuum pressure values within the chamber (col.4, lines 36-39 and col.7, lines 52-56).

6. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carman et al (U.S.P.N. 6,284,193) in view of Jacobs et al (U.S.P.N. 6,325,972) as applied to claim 1 and further in view of Shapiro (U.S.P.N. 3,719,017).

With respect to claims 9-10, both the Carman reference and the Jacobs reference fail to teach repeating the following steps: applying a vacuum, humidifying, supplying ozone-containing gas and maintaining the pressure in the chamber over a preselected time interval. The Shapiro reference, which is in the art of sterilizing packaging devices by using ozone, teaches repeating the exhausting (vacuuming) and refilling of the container with ozone mist (col.2, lines 11-15 and col.4, lines 61-64). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Carman reference by repeating the steps of vacuuming, humidifying, supplying ozone and maintaining pressure in the chamber over a preselected time interval in order to completely expel air from the container and surround the article therein with the sterilizing medium as taught by the Shapiro reference (col.2, lines 11-15).

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carman et al (U.S.P.N. 6,284,193) in view of Jacobs et al (U.S.P.N. 6,325,972) as applied to claim 12 and further in view of Shapiro (U.S.P.N. 3,719,017).

With respect to claim 14, the Carman reference teaches the following: a chamber door (figure 2:2), a humidifier (figure 2:12), means for controlling the chamber temperature (figure 2:11), means for controlling the door (col.1, lines 29-31) and means for controlling the humidifier (the reference must intrinsically include some humidity

control means in order to introduce and stop the introduction of humidity into the chamber); however, both the Carman reference and the Jacobs reference fail to teach the use of a water reservoir. The Shapiro reference, which is in the art of sterilizing packaging devices by using ozone, teaches that the source of water vapor is from water reservoir (figure 2:WR). The specification on page 27 does not provide any benefits for using a water reservoir. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Carman reference by substituting water vapor source for water reservoir as evidenced by the Shapiro reference (figure 2:WR).

Allowable Subject Matter

8. Claims 24-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

9. Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

On page 8 of the Remarks section, applicant argues that, "In contrast, the process of the present invention is a batch process, wherein sterilization gas is injected into the chamber and maintained in the chamber for a selected residence time." The instant claims do not recite the "batch process" feature. Furthermore, ozone gas in the Carman reference is injected into the chamber (figure 2:6 and 1) and maintained in the chamber for a selected residence time (col.7, lines 60-67).

On page 9 of the Remarks section, applicant argues that, "However, as mentioned, the method of the present application does employ ozone in a static fashion." Again, the limitation "static fashion" is not recited in the instant claims.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JOHN KIM can be reached on (571) 272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
08/02/2005

JOHN KIM
SUPERVISORY PATENT EXAMINER